

WHAT IS CLAIMED IS:

1. An isolated, substantially pure, or recombinant protein preparation of a telomerase reverse transcriptase protein, said protein characterized by having an amino acid sequence:

Trp-R<sub>1</sub>-X<sub>7</sub>-R<sub>1</sub>-R<sub>1</sub>-R<sub>2</sub>-X-Phe-Phe-Tyr-X-Thr-Glu-X<sub>8,9</sub>-R<sub>3</sub>-R<sub>3</sub>-Arg-R<sub>4</sub>-X<sub>2</sub>-Trp

where X is any amino acid and a subscript refers to the number of consecutive residues, R<sub>1</sub> is leucine or isoleucine, R<sub>2</sub> is glutamine or arginine, R<sub>3</sub> is phenylalanine or tyrosine, and R<sub>4</sub> is lysine or histidine.

2. An isolated, substantially pure or recombinant nucleic acid that encodes a telomerase reverse transcriptase protein, said protein characterized by having an amino acid sequence:

Trp-R<sub>1</sub>-X<sub>7</sub>-R<sub>1</sub>-R<sub>1</sub>-R<sub>2</sub>-X-Phe-Phe-Tyr-X-Thr-Glu-X<sub>8,9</sub>-R<sub>3</sub>-R<sub>3</sub>-Arg-R<sub>4</sub>-X<sub>2</sub>-Trp

where X is any amino acid and a subscript refers to the number of consecutive residues, R<sub>1</sub> is leucine or isoleucine, R<sub>2</sub> is glutamine or arginine, R<sub>3</sub> is phenylalanine or tyrosine, and R<sub>4</sub> is lysine or histidine.

3. The protein preparation of claim 1 that is a recombinant telomerase reverse transcriptase protein having an amino acid sequence identical to the amino acid sequence of a naturally occurring telomerase reverse transcriptase protein selected from the group of organisms consisting of *Tetrahymena*, *Euploites*, *S. pombe*, and humans.

4. The nucleic acid of claim 2 that is a recombinant nucleic acid having a nucleotide sequence that encodes a recombinant protein of claim 3.

5. The nucleic acid of claim 4 that encodes hTERT.

6. A method of detecting a human telomerase reverse transcriptase (hTERT) gene product in a biological sample comprising:

a) contacting the biological sample with a probe that specifically binds the gene product, wherein the probe and the gene product form a complex, and detecting the complex; or,

b) specifically amplifying the gene product in the biological sample, wherein said gene product is a nucleic acid, and detecting the amplification product;

wherein the presence of the complex or amplification product is correlated with the presence of the hTERT gene product in the biological sample.

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7. The method of claim 6, wherein the gene product is an RNA.

8. The method of claim 7, wherein the probe is a nucleic acid.

15 9. The method of claim 6, wherein the gene product is a polypeptide.

10. The method of claim 9, wherein the probe is an antibody.

11. The method of claim 6, wherein the biological sample is from a patient.

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12. The method of claim 6, wherein the biological sample comprises at least one cell from an *in vitro* cell culture.

13. The method of claim 12, wherein the cell is human.

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14. A method of detecting the presence of at least one immortal human cell in a biological sample comprising human cells, said method comprising the steps:

a) obtaining the biological sample comprising human cells; and,

b) detecting the presence in the sample of a cell having a high level of an hTERT gene product,

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wherein the presence of a cell having a high level of the hTERT gene product is correlated with the presence of immortal cells in the biological sample.

15. A method for diagnosing a telomerase-related condition in a patient, comprising:
- a) obtaining a cell or tissue sample from the patient;
  - b) determining the amount of a human telomerase reverse transcriptase (hTERT) gene product in the cell or tissue; and,
  - c) comparing the amount of hTERT gene product in the cell or tissue with the amount in a healthy cell or tissue of the same type;

wherein a different amount of hTERT gene product in the sample from the patient and the healthy cell or tissue is diagnostic of a telomerase-related condition.

16. The method of claim 15 wherein the telomerase-related condition is cancer.

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17. A method of diagnosing cancer in a patient, said method comprising:

- a) obtaining a biological sample from the patient; and,
- b) detecting a human telomerase reverse transcriptase (hTERT) gene product in the patient sample;

20 wherein the detection of the hTERT gene product in the sample is correlated with a diagnosis of cancer.

18. A method of diagnosing cancer in a patient, said method comprising:

- a) obtaining a patient sample;
- b) determining the amount human telomerase reverse transcriptase (hTERT) gene product in the patient sample; and,
- c) comparing the amount of hTERT gene product with a normal value for the sample,

wherein an amount of the hTERT gene product in the patient that is greater than the normal value is diagnostic of cancer.

19. A method of diagnosing cancer in a patient, said method comprising:

- a) obtaining a patient sample containing at least one cell;
- b) determining the amount of a hTRT gene product in a cell in the sample;

and,

5 c) comparing the amount of hTRT gene product in the cell with a normal value for the cell,

wherein an amount of the hTRT gene product greater than the normal value is diagnostic of cancer.

10 20. The method of claim 19, wherein the sample is believed to contain at least one malignant cell.

21. A method of providing a prognosis for a cancer patient, said method comprising:

15 a) determining the amount of hTRT gene product in a cancer cell obtained from the patient; and,

b) comparing the amount of hTRT in the cancer cell with a prognostic value of hTRT per cancer cell consistent with a prognosis for the cancer;

whereby an amount of hTR per cell in the sample that is at the prognostic  
20 value provides the particular prognosis.

22. A method for monitoring the ability of an anticancer treatment to reduce the proliferative capacity of cancer cells in a patient, said method comprising:

a) making a first measurement of the amount of an hTRT gene product in at least one  
25 cancer cell from the patient;

b) making a second measurement of the level of the hTRT gene product in at least one cancer cell from the patient, wherein the anticancer treatment is administered to the patient before or at the same time as the second measurement; and,

c) comparing the first and second measurements,  
30 wherein a lower level of the hTRT gene product in the second measurement is

correlated with the ability of an anticancer treatment to reduce the proliferative capacity of cancer cells in the patient.

23. A kit for the detection of a hTERT gene or gene product, said kit comprising a container containing a molecule selected from an hTERT nucleic acid or subsequence thereof, an hTERT polypeptide or subsequence thereof, and an anti-hTERT antibody.

24. A method for increasing the proliferative capacity of a vertebrate cell, said method comprising:

introducing a recombinant polynucleotide into the cell,  
wherein said polynucleotide comprises a sequence encoding a human telomerase reverse transcriptase (hTERT) polypeptide,  
and wherein said sequence is operably linked to a promoter.

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25. The method of claim 24, wherein the hTERT has telomerase catalytic activity.

26. The method of claim 24, wherein the hTERT polypeptide has a sequence of  
SEQ ID NO:2.

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27. The method of claim 24, wherein the cell is from a mammal.

28. The method of claim 27, wherein the cell is human.

25 29. The method of claim 28, wherein the cell is from a human patient.

30. The method of claim 28 or 29, wherein the cell is cultured *in vitro*.

31. The method of claim 29, further comprising the step of reintroducing the cell  
into a human patient.

32. The method of claim 24, wherein the recombinant polynucleotide is introduced into at least one cell in a patient using a gene therapy vector.

33. The method of claim 24, further comprising introducing into the cell a polynucleotide comprising a sequence encoding human telomerase RNA, wherein the polynucleotide is operably linked to a promoter.

34. A method for increasing the proliferative capacity of a vertebrate cell, said method comprising introducing into the cell an effective amount of a human telomerase reverse transcriptase (hTERT) polypeptide.

35. The method of claim 34, wherein the hTERT polypeptide has telomerase catalytic activity.

15 36. A pharmacological composition comprising a pharmaceutically acceptable carrier and a molecule selected from: a hTERT polypeptide, a polynucleotide encoding a hTERT polypeptide, and a hTERT nucleic acid or subsequence thereof.

37. A method for treatment of a condition associated with an elevated level of telomerase activity within a cell, comprising introducing into said cell a therapeutically effective amount of an inhibitor of said telomerase activity, wherein said inhibitor is an hTERT polypeptide or a hTERT polynucleotide.

38. The method of claim 37, wherein the inhibitor is a polypeptide comprising the sequence of SEQ ID NO:2 or 4, or a subsequence thereof.

39. The method of claim 38, wherein the polypeptide comprises nonstandard or derivatized residues.

30 40. The method of claim 38, wherein the polypeptide inhibits binding of

endogenous hTERT to hTR.

41. The method of claim 37, wherein the step of introducing the inhibitor into the cell comprises transforming the cell or an ancestor with a polynucleotide encoding the hTERT polypeptide or a hTERT polynucleotide.

42. A vaccine comprising a hTERT polypeptide and an adjuvant.

43. Substantially pure human telomerase comprising human telomerase reverse transcriptase (hTERT) and comprising human telomerase RNA (hTR).

44. The human telomerase of claim 43 that is at least about 95% homogeneous.

45. The human telomerase of claim 43 that is from a cell.

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